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YY/T 1710-2020

Disposable Abdominal Trocars

一次性使用腹部穿刺器

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Disposable Abdominal Trocars

1 Scope

This Standard specifies the structure, materials, requirements, test methods, type inspection, labeling, instruction manual and packaging of disposable abdominal trocars.

This Standard is applicable to disposable abdominal trocars (hereinafter referred to as trocars) that puncture human abdominal wall tissues during laparoscopic surgery to establish artificial pneumoperitoneum and operate surgical instrument channel.

2 Normative References

The following documents are indispensable to the application of this document. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 1220 Stainless Steel Bars

GB/T 1962.2 Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock Fittings

GB/T 3280 Cold Rolled Stainless Steel Plate, Sheet and Strip

GB/T 4340.1 Metallic Materials - Vickers Hardness Test - Part 1: Test Method

GB/T 6682-2008 Water for Analytical Laboratory Use - Specification and Test Methods

GB/T 12672 Acrylonitrile-butadiene-styrene (ABS) Resin

GB/T 14233.1-2008 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 1: Chemical Analysis Methods

GB/T 16886 (all parts) Biological Evaluation of Medical Devices

YY/T 0149-2006 Medical Instruments of Stainless Steel - Test Methods of Corrosion Resistance

YY/T 0466.1 Medical Devices - Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements

YY/T 0806 Polycarbonate Material for Manufacture of Infusion, Transfusion and Injection Equipment for Medical Use and Other Medical Devices

4 Requirements

4.1 Appearance

4.1.1 The outer surface of the trocars shall be smooth and clean. There shall be no defects, such as: burrs, bubbles, impurities, cracks and sintered substances, etc.

4.1.2 The surface of the trocars shall not have visible accumulation of lubricant.

4.1.3 The specification marking on the body of the trocars shall be clearly visible.

4.1.4 If there is a puncturing knife at the tip of the puncturing lever, then, the puncturing knife shall be flat, and there shall be no rust, sharp edges, burrs or obvious pitting. The cutting edge of the puncturing knife shall be free of nicks, white edges, wire edges and cracks, etc.

4.2 Dimensions

The inner diameter ϕ and working length L of the puncturing sleeve casing of the trocars shall comply with the stipulations of Table 1.

4.3 Surface Roughness

If there is a puncturing knife at the tip of the puncturing lever, then, the surface roughness of the cutting edge surface of the puncturing knife $Ra \leq 0.8$ μm.

4.4 Hardness

If there is a skin-puncturing knife at the tip of the puncturing lever, then, the puncturing knife shall receive thermal treatment; its hardness shall be not less than 650HV10.

4.5 Flexibility

4.5.1 The air injection valve of the trocars shall be able to be flexibly opened and closed; there shall be no obstruction or jamming.

4.5.2 If the sheath cap is detachable, then, its assembly and disassembly shall be flexible and convenient; there shall be no obstruction or jamming.

4.5.3 If there is a puncturing knife at the tip of the puncturing lever, then, the puncturing knife shall be able to be flexibly retracted; there shall be no obstruction or jamming.

4.6 Coordination Performance

4.6.1 The puncturing sleeve and the puncturing lever shall properly coordinate with each other. There shall be no jamming when plugging or unplugging.

shall be not greater than 10 μg/g.

4.14 Dissolved Precipitates of Polymer Materials of Parts in Contact with Patient

4.14.1 Appearance (turbidity and color)

The dissolution liquid shall be colorless and transparent, and there shall be no visible foreign objects.

4.14.2 pH

The pH difference between the dissolution liquid and the blank control solution of the same batch shall be ≤ 2.0.

4.14.3 Heavy metals

The total content of heavy metals that can be dissolved in the dissolution liquid shall be ≤ 5 μg/mL.

4.14.4 Reducing substance

Compare the dissolution liquid with the same batch of blank control solution of an equal volume; the difference in the amount of consumed potassium permanganate solution [c (1/5$KMnO_4$) = 0.01 mol/L] shall be ≤ 2.0 mL.

4.14.5 Evaporation residue

The total dry residue of the dissolution liquid shall be ≤ 2.0 mg.

4.15 Package Marking and Instruction Manual

4.15.1 The single package of the trocars shall have a marking that complies with the stipulations of 3.1.2.

4.15.2 The instruction manual of the trocars shall include the specifications of devices that can be used together with the trocars.

4.15.3 If the puncturing knife has the function of skin-puncturing, then, it shall be clearly described in the instruction manual.

4.16 Biological Evaluation

The trocars shall receive biological evaluation in accordance with the stipulations of the series standards of GB/T 16886, and there shall be no biocompatibility hazards.

inserted into the fit clearance. It shall comply with the stipulations of 4.6.2.

5.6.3 Imitate the action of use. Conduct visual observation. It shall comply with the stipulations of 4.6.3.

5.7 Connection Firmness Test

5.7.1 At the junction of the detachable sheath cap and the puncturing sleeve, apply an axial static tensile force of 50 N to any component consecutively for 10 s. It shall comply with the stipulations of 4.7.1.

5.7.2 Imitate the action of use; fix the casing; rotate and draw the casing seat. It shall comply with the stipulations of 4.7.2.

5.7.3 At the junction of the puncturing lever, apply an axial static tensile force of 15 N to any component consecutively for 10 s. It shall comply with the stipulations of 4.7.3.

5.8 Air Chocking and Sealing Performance Test

The test method is shown in Appendix A. It shall comply with the stipulations of 4.8.

5.9 Connector of Air Injection Valve

The Luer locking connecting of the air injection valve shall be tested in accordance with GB/T 1962.2. It shall comply with the stipulations of 4.9.

5.10 Puncturing and Plugging / Unplugging Performance

The evaluation and test methods for the puncturing and plugging / unplugging performance are shown in Appendix B and Appendix C.

NOTE: the method in the appendix is only a test method for the uniform evaluation of the puncturing performance and plugging / unplugging performance of the trocars.

5.11 Corrosion Resistance

Corrosion resistance is tested in accordance with the stipulations of the boiling water test method in YY/T 0149-2006. It shall comply with the stipulations of 4.11.

5.12 Sterility

In accordance with the “sterility test method” in the *Pharmacopoeia of the People’s Republic of China* (Version 2015 • Vol. 4), conduct the test. It shall comply with the stipulations of 4.12.

5.13 Residual Ethylene Oxide

In accordance with Chapter 9 “Gas Chromatography” in GB/T 14233.1-2008, conduct

Appendix A

(normative)

Test Method for Air Chocking and Sealing Performance

A.1 Definition

Air chocking performance: evaluate the air chocking performance of the puncturing sleeve after the puncturing lever is pulled out of the puncturing sleeve.

Sealing performance: evaluate the sealing performance of the puncturing sleeve after plugging the standard lever of the simulated endoscopic instrument into the puncturing sleeve.

A.2 Test Equipment

A.2.1 Pressurizing device, including air source, pressure gauge (with a precision of 0.1 kPa) and connecting pipeline.

A.2.2 Water container with a flat bottom.

A.2.3 The requirements for the standard big / small lever are as follows:

a) Solid stainless steel lever;

b) The diameter of the instrument lever of the smallest and the largest specifications applicable to the trocars with an equal diameter has an error of ± 0.1 mm;

c) The value of surface roughness *R*a is not greater than 0.4 μm;

d) The puncturing end is rounded;

e) The length is not less than the working length of the puncturing lever.

A.3 Test Procedures

A.3.1 Test procedures of air chocking performance:

a) Connect the tip of the trocar after plugging the puncturing lever to the pressurizing device; ensure that there is no leakage at the junction;

b) Close the air injection valve of the trocar; block the side hole of the casing of the puncturing sleeve and the air hole at the end of the puncturing lever;

Appendix B

(informative)

Evaluation and Test Method for Puncturing Performance

B.1 Definition

Puncture force: the maximum force required by the trocar to puncture the test material at a certain speed.

B.2 Test Equipment and Test Material

B.2.1 Material testing machine

B.2.1.1 Accuracy: 0.1 N.

B.2.1.2 Test condition: puncture speed 100 mm/min.

B.2.2 Fixture

Ensure that the trocar and the test material are firmly fixed. The lower part of the puncture is supported by a ring-shaped block. Under the condition that sufficient supporting force is provided to the punctured object, the middle space of the ring-shaped block shall ensure that the puncturing lever can completely penetrate into the punctured object.

B.2.3 Test material

The abdominal tissue of pigs, with skin, fresh-frozen for no more than 48 h. The size of one side is at least 10 times the outer diameter of the casing of the puncturing sleeve.

B.3 Test Procedures

B.3.1 Test procedures of a trocar with the skin-puncturing function:

a) Clamp the trocar and the test material (B.2.3) on the fixture (B.2.2);

b) Actuate the testing machine (B.2.1); use the trocar to puncture the test material (B.2.3), until the casing of the puncturing sleeve completely enters the test material (B.2.3), then, stop; record the maximum force value, which is the puncture force.

B.3.2 Test procedures of a trocar without the skin-puncturing function:

a) Clamp the trocar and the test material (B.2.3) on the fixture (B.2.2);

Appendix C

(informative)

Evaluation and Test Method for Plugging / Unplugging Performance

C.1 Definition

Plugging force / unplugging force: the maximum force required by the puncturing lever of the trocar and the standard big / small lever to plug into / unplug from the casing of the puncturing sleeve.

C.2 Test Equipment

C.2.1 Material testing machine

C.2.1.1 Accuracy: 0.1 N.

C.2.1.2 Test condition: puncture / unplug speed 100 mm/min; puncture stroke L-10 mm (if the structure of the trocar cannot satisfy L-10 mm, it is allowed to modify the stroke; the modification needs to be indicated in the test report).

C.2.2 Fixture

Ensure that the casing of the puncturing sleeve of the trocar is not subject to force in the radial direction, and firmly fixed in the axial direction.

C.3 Procedures

C.3.1 Clamp the casing of the puncturing sleeve and the puncturing lever on the fixture (C.2.2); ensure that the axis of the puncturing lever coincides with the axis of the casing of the puncturing sleeve.

C.3.2 Adjust the position of the upper clamp, so as to confirm that the tip of the puncturing lever is in contact with the upper sealing ring of the casing of the puncturing sleeve, but not under force, as it is shown in Figure C.1.

NOTE: if there is a positional correspondence between the puncturing lever and the casing, ensure that the relative position of the puncturing lever and the casing is correct.

C.3.3 Actuate the testing machine (C.2.1). After the puncturing lever is plugged into the casing of the puncturing sleeve to the set stroke position, stop and record the maximum force value, which is the plugging force of the puncturing lever, as it is shown in Figure C.2.

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